MANIPUR GAZETTE

E X T R A O R D I N A R Y
PUBLISHED BY AUTHORITY

No. 331 Imphal, Thursday, February 26, 2026 Phalguna 7, 1947)

GOVERNMENT OF MANIPUR
SECRETARIAT: HEALTH DEPARTMENT

N O T I F I C A T I O N

Imphal, the 27th January, 2026.

No. MED-1202/7/2022-HS-HEALTH: The following Rules of Government of India, Ministry of Health and Family Welfare, New Delhi are republished for general Information.

By Orders & in the name of Governor;

BANTEE SINGH KONTHOUJAM,
Joint Secretary (Health & FW),
Government of Manipur.

MINISTRY OF HEALTH AND FAMILY WELFARE

NOTIFICATION

New Delhi, the 27th March, 2014

G.S.R. 218 (E).— In exercise of the powers conferred by section 24 of the Transplantation of Human Organs Act, 1994 (42 of 1994) and in supersession of the Transplantation of Human Organs Rules, 1995, except as respects things done or omitted to be done before such supersession, the Central Government hereby makes the following rules, namely: -

1. **Short title and commencement** — (1) These rules may be called the Transplantation of Human Organs and Tissues Rules, 2014.

(2) They shall come into force on the date of their publication in the Official Gazette.

2. **Definitions:** - In these rules unless the context otherwise requires,—

(a) "Act" means the Transplantation of Human Organs Act, 1994;

(b) "cadaver(s)", "organ(s)" and "tissue(s)" means human cadaver(s), human organ(s) and human tissue(s), respectively;

(c) "competent authority" means the Head of the institution or hospital carrying out transplantation or committee constituted by the head of the institution or hospital for the purpose;

(d) "Form" means a Form annexed to these rules;

(e) National Accreditation Board for Testing and Calibration Laboratories (NABL) means the autonomous body established under the aegis of Department of Science and Technology, Government of India with the objective to provide Government, Regulators and Industry with a scheme of laboratory accreditation through third-party assessment for formally recognising the technical competence of laboratories and the accreditation Services are provided for testing and calibration of medical laboratories in accordance with International Organisation for Standardisation (ISO) Standards;

(f) "the technician who can enucleate cornea" means the technician with any of the following qualifications and experience who can harvest corneas (enucleate eyeballs or excise corneas), namely:-

1. Ophthalmologists possessing a Doctor of Medicine (M.D) or Master of Surgery (M.S) in Ophthalmology or Diploma in Ophthalmology (D.O.); and
2. registered Doctors from all recognised systems of medicine, Nurses, Paramedical Ophthalmic Assistant, Ophthalmic Assistant, Optometrists, Refractionists, Paramedical Worker or Medical Technician with recognised qualification from all recognised systems of medicine, provided the person is duly trained to enucleate a donated cornea or eye from registered, authorised and functional eye Bank or Government medical college and, the training certificate should mention that he has acquired the required skills to independently conduct enucleation of the eye or removal of cornea from a cadaver;

(g) words and expressions used and not defined in these rules, but defined in the Act, shall havethe same meanings, respectively, assigned to them in the Act.

3. **Authority for removal of human organs or tissues.—**Subject to the provisions of Section 3 of the Act, a living person may authorise the removal of any organ or tissue of his or her body during his or her lifetime as per prevalent medical practices, for therapeutic purposes in the manner and on such conditions as specified in Form 1, 2 and 3.

4. **Panel of experts for brain-stem death certification.—**For the purpose of certifying the brain-

stem death, the Appropriate Authority shall maintain a panel of experts, in accordance with the provisions of the Act, to ensure efficient functioning of the Board of Medical Experts and it remains fully operational.

5. **Duties of the registered medical practitioner.— (1)** The registered medical practitioner of the hospital having Intensive Care Unit facility, in consultation with transplant coordinator, if available, shall ascertain, after certification of brain stem death of the person in Intensive Care Unit, from his or her adult near relative or, if near relative is not available, then, any other person related by blood or marriage, and in case of unclaimed body, from the person in lawful possession of the body the following, namely:-

(a) whether the person had, in the presence of two or more witnesses (at least one of who is a near relative of such person), unequivocally authorised before his or her death as specified in Form 7 or in documents like driving license, etc. wherein the provision for donation may be incorporated after notification of these rules, the removal of his or her organ(s) or tissue(s) including eye, after his or her death, for therapeutic purposes and there is no reason to believe that the person had subsequently revoked the aforesaid authorisation;

(b) where the said authorisation was not made by the person to donate his or her organ(s) or tissue(s) after his or her death, then the registered medical practitioner in consultation with the transplant coordinator, if available, shall make the near relative or person in lawful possession of the body, aware of the option to authorise or decline the donation of such human organs or tissues or both (which can be used for therapeutic purposes) including eye or cornea of the deceased person and a declaration or authorisation to this effect shall be ascertained from the near relative or person in lawful possession of the body as per Form 8 to record the status of consent, and in case of an unclaimed body, authorisation shall be made in Form 9 by the authorised official as per sub-section (1) of section 5 of the Act;

(c) after the near relative or person in lawful possession of the body authorises removal and gives consent for donation of human organ(s) or tissue(s) of the deceased person, the registered medical practitioner through the transplant coordinator shall inform the authorised registered Human Organ Retrieval Centre through authorised coordinating organisation by available documentable mode of communication, for removal, storage or transportation of organ(s) or tissue(s).

(2) The above mentioned duties shall also apply to the registered medical practitioner working in an Intensive Care Unit in a hospital not registered under this Act, from the date of notification of these rules.

(3) The registered medical practitioner shall, before removing any human organ or tissue from a living donor, shall satisfy himself –

(a) that the donor has been explained of all possible side effects, hazards and complications and that the donor has given his or her authorisation in appropriate Form 1 for near relative donor or Form 2 for spousal donor or Form 3 for donor other than near relative;

(b) that the physical and mental evaluation of the donor has been done, he or she is in proper state of health and it has been certified that he or she is not mentally challenged and that he or she is fit to donate the organ or tissue:

Provided that in case of doubt regarding mentally challenged status of the donor the registered medical practitioner may get the donor examined by a psychiatrist and the registered medical practitioner shall sign the certificate as prescribed in Form 4 for this purpose;

(c) that the donor is a near relative of the recipient, as certified in Form 5, and that he or she has submitted an application in Form 11 jointly with the recipient and that the proposed donation has been approved by the competent authority as defined at rule 2(c)

and specified in Form 19 and that the necessary documents as prescribed and medical tests, as required, to determine the factum of near relationship, have been examined to the satisfaction of the registered medical practitioner and the competent authority;

(d) that in case the recipient is spouse of the donor, the donor has given a statement to the effect that they are so related by signing a certificate in Form 2 and has submitted an application in Form 11 jointly with the recipient and that the proposed donation has been approved by the competent authority under the provisions of sub-rule (2) of rule 7;

(e) that in case of a donor who is other than a near relative and has signed Form 3 and submitted an application in Form 11 jointly with the recipient, the permission from the Authorisation Committee for the said donation has been obtained;

(f) that if a donor or recipient is a foreign national, the approval of the Authorisation Committee for the said donation has been obtained;

(g) living organ or tissue donation by minors shall not be permitted except on exceptional medical grounds to be recorded in detail with full justification and with prior approval of the Appropriate Authority and the State Government concerned.

(4) A registered medical practitioner, before removing any organ or tissue from the body of a person after his or her death (deceased donor), in consultation with transplant coordinator, shall satisfy himself the following, namely:-

(a) that caution has been taken to make inquiry, from near relative or person in lawful possession of the body of a person admitted in Intensive Care Unit, only after certification of Brain Stem death of the person that the donor had, in the presence of two or more witnesses (at least one of whom is a near relative of such person),unequivocally authorised before his or her death as specified in Form 7 or in documents like driving license etc. (wherein the provision for donation may be incorporated after notification of these rules), the removal of his or her organ(s) or tissue(s) after his or her death, for therapeutic purposes and it has been ascertained that the donor has not subsequently revoked the aforesaid authorisation, and the consent of near relative or person in lawful possession of the body shall also be required notwithstanding the authorisation been made by deceased donor:

Provided that if the deceased person who had earlier given authorisation but had revoked it subsequently and if the person had given in writing that his organ should not be removed after his death, then, no organ or tissue will be removed even if consent is given by the near relative or person in lawful possession of the body;

(b) that the near relative of the deceased person or the person lawfully in possession of the body of the deceased donor has signed the declaration as specified in Form 8.

(c) that in the case of brain-stem death of the potential donor, a certificate as specified in Form 10 has been signed by all the members of the Board of Medical Experts referred to in sub-section (6) of section 3 of the Act:

Provided that where a neurologist or a neurosurgeon is not available, an anesthetist or intensivist who is not part of the transplant team nominated by the head of the hospital duly empanelled by Appropriate Authority may certify the brain stem death as a member of the said Board;

(d) that in the case of brain-stem death of a person of less than eighteen years of age, a certificate specified in Form 10 has been signed by all the members of the Board of Medical Experts referred to in sub-section (6) of section 3 of the Act and an authority as specified in Form 8 has been signed by either of the parents of such person or any near relative authorised by the parent.

6. Procedure for donation of organ or tissue in medicolegal cases.— (1) After the authority for

removal of organs or tissues, as also the consent to donate organs from a brain-stem dead donor are obtained, the registered medical practitioner of the hospital shall make a request to the Station House Officer or Superintendent of Police or Deputy Inspector General of the area either directly or through the police post located in the hospital to facilitate timely retrieval of organs or tissue from the donor and a copy of such a request should also be sent to the designated post mortem doctor of area simultaneously.

(2) It shall be ensured that, by retrieving organs, the determination of the cause of death is not jeopardised.

(3) The medical report in respect of the organs or tissues being retrieved shall be prepared at the time of retrieval by retrieving doctor (s) and shall be taken on record in postmortem notes by the registered medical practitioner doing postmortem.

(4) Wherever it is possible, attempt should be made to request the designated postmortem registered medical practitioner, even beyond office timing, to be present at the time of organ or tissue retrieval.

(5) In case a private retrieval hospital is not doing post mortem, they shall arrange transportation of body along with medical records, after organ or tissue retrieval, to the designated postmortem centre and the post mortem centre shall undertake the postmortem of such cases on priority, even beyond office timing, so that the body is handed over to the relatives with least inconvenience.

7. Authorisation Committee.—(1) The medical practitioner who will be part of the organ transplantation team for carrying out transplantation operation shall not be a member of the Authorisation Committee constituted under the provisions of clauses (a) and (b) of sub-section(4) of section 9 of the Act.

(2) When the proposed donor or recipient or both are not Indian nationals or citizens whether near relatives or otherwise, the Authorisation Committee shall consider all such requests and the transplantation shall not be permitted if the recipient is a foreign national and donor is an Indian national unless they are near relatives.

(3) When the proposed donor and the recipient are not near relatives, the Authorisation Committee shall,-

(i) evaluate that there is no commercial transaction between the recipient and the donor and that no payment has been made to the donor or promised to be made to the donor or any other person;

(ii) prepare an explanation of the link between them and the circumstances which led to the offer being made;

(iii) examine the reasons why the donor wishes to donate;

(iv) examine the documentary evidence of the link, e.g. proof that they have lived together, etc.;

(v) examine old photographs showing the donor and the recipient together;

(vi) evaluate that there is no middleman or tout involved;

(vii) evaluate that financial status of the donor and the recipient by asking them to give appropriate evidence of their vocation and income for the previous three financial years and any gross disparity between the status of the two must be evaluated in the backdrop of the objective of preventing commercial dealing;

(viii) ensure that the donor is not a drug addict;

(ix) ensure that the near relative or if near relative is not available, any adult person related to donor by blood or marriage of the proposed unrelated donor is interviewed regarding awareness about his or her intention to donate an organ or tissue, the authenticity of the link between the donor and the recipient, and the reasons for donation, and any strong

views or disagreement or objection of such kin shall also be recorded and taken note of.

(4) Cases of swap donation referred to under subsection (3A) of section 9 of the Act shall be approved by Authorisation Committee of hospital or district or State in which transplantation is proposed to be done and the donation of organs shall be permissible only from near relatives of the swap recipients.

(5) When the recipient is in a critical condition in need of life saving organ transplantation within a week, the donor or recipient may approach hospital in-charge to expedite evaluation by the Authorisation Committee.

8. **Removal and preservation of organs or tissues.—**The removal of the organ(s) or tissue(s) shall be permissible in any registered retrieval or transplant hospital or centre and preservation of such removed organ(s) or tissue(s) shall be ensured in registered retrieval or transplant centre or tissue bank according to current and accepted scientific methods in order to ensure viability for the purpose of transplantation.

9. **Cost for maintenance of cadaver or retrieval or transportation or preservation of organs or tissues.—**The cost for maintenance of the cadaver (brain-stem dead declared person), retrieval of organs or tissues, their transportation and preservation, shall not be borne by the donor family and may be borne by the recipient or institution or Government or non-Government organisation or society as decided by the respective State Government or Union territory Administration.

10. **Application for living donor transplantation.—** (1) The donor and the recipient shall make jointly an application to grant approval for removal and transplantation of a human organ, to the competent authority or Authorisation Committee as specified in Form 11 and the papers for approval of transplantation would be processed by the registered medical practitioner and administrative division of the Institution for transplantation.

(2) The competent authority or Authorisation Committee shall take a decision on such application in accordance with the rule 18.

(3) If some State wants to merge Form 11 with Form 1, Form 2 or Form 3, they may do so, provided the content of the recommended Forms are covered in the merged Form and the same is approved by the State Government concerned.

11. **Composition of Authorisation Committees.—(1)** There shall be one State level Authorisation Committee.

(2) Additional Authorisation Committees in the districts or Institutions or hospitals may be set up as per norms given below, which may be revised from time to time by the concerned State Government or Union territory Administration by notification.

(3) No member from transplant team of the institution should be a member of the respective Authorisation Committee.

(4) Authorisation Committee should be hospital based if the number of transplants is twenty five or more in a year at the respective transplantation centres, and if the number of organ transplants in an institution or hospital are less than twenty-five in a year, then the State or District level Authorisation Committee would grant approval(s).

12. **Composition of hospital based Authorisation Committees.—** The hospital based Authorisation Committee shall, as notified by the State Government in case of State and by the Union territory Administration in case of Union territory, consist of,—

(a) the Medical Director or Medical Superintendent or Head of the institution or hospital or a senior medical person officiating as Head - Chairperson;

(b) two senior medical practitioners from the same hospital who are not part of the transplant team – Member;

(c) two persons (preferably one woman) of high integrity, social standing and credibility, who

have served in high ranking Government positions, such as in higher judiciary, senior cadre of police service or who have served as a reader or professor in University Grants Commission approved University or are self-employed professionals of repute such as lawyers, chartered accountants, doctors of Indian Medical Association, reputed non-Government organisation or renowned social worker - Member;

(d) Secretary (Health) or nominee and Director Health Services or nominee from State Government or Union territory Administration - Member.

13. Composition of State or District Level Authorisation Committees.— The State or District Level Authorisation Committee shall, as notified by the State Government in case of State and by the Union territory Administration in case of Union territory, consist of,—

(a) a Medical Practitioner officiating as Chief Medical Officer or any other equivalent post in the main or major Government hospital of the District – Chairperson;

(b) two senior registered medical practitioners to be chosen from the pool of such medical practitioners who are residing in the concerned District and who are not part of any transplant team– Member;

(c) two persons (preferably one woman) of high integrity, social standing and credibility, who have served in high ranking Government positions, such as in higher judiciary, senior cadre of police service or who have served as a reader or professor in University Grants Commission approved University or are self-employed professionals of repute such as lawyers, chartered accountants, doctors of Indian Medical Association, reputed non-Government organisation or renowned social worker - Member;

(d) Secretary (Health) or nominee and Director Health Services or nominee from State Government or Union territory Administration–Member :

Provided that effort shall be made by the State Government concerned to have most of the members' ex-officio so that the need to change the composition of Committee is less frequent.

14. Verification of residential status, etc.—When the living donor is unrelated and if donor or recipient belongs to a State or Union territory, other than the State or Union territory where the transplantation is proposed to be undertaken, verification of residential status by Tehsildar or any other authorised officer for the purpose with a copy marked to the Appropriate Authority of the State or Union territory of domicile of donor or recipient for their information shall be required, as per Form 20 and in case of any doubt of organ trafficking, the Appropriate Authority of the State or Union territory of domicile or the Tehsildar or any other authorised officer shall inform police department for investigation and action as per the provisions of the Act.

15. Quorum of Authorisation Committee.— The quorum of the Authorisation Committee should be minimum four and the quorum shall not be complete without the participation of the Chairman, the presence of Secretary (Health) or nominee and Director of Health Services or nominee.

16. Format of approval of Authorisation Committee.— The format of the Authorisation Committee approval should be uniform in all the institutions in a State and the format may be notified by the respective State Government as per Form 18.

17. Scrutiny of applications by Authorisation Committee.— (1) Secretariat of the Authorisation Committee shall circulate copies of all applications received from the proposed donors and recipients to all members of the Committee along with all annexures, which may have been filed along with the applications.

(2) At the time of the meeting, the Authorisation Committee should take note of all relevant contents and documents in the course of its decision making process and in the event any document or information is found to be inadequate or doubtful, explanation should be sought

from the applicant and if it is considered necessary that any fact or information requires to be verified in order to confirm its veracity or correctness, the same be ascertained through the concerned officer(s) of the State Government or Union territory Administration.

18. Procedure in case of near relatives.— (1) Where the proposed transplant of organs is between near relatives related genetically, namely, grandmother, grandfather, mother, father, brother, sister, son, daughter, grandson and granddaughter, above the age of eighteen years, the competent authority as defined at rule 2(c) or Authorisation Committee (in case donor or recipient is a foreigner) shall evaluate;

(i) documentary evidence of relationship e.g. relevant birth certificates, marriage certificate, other relationship certificate from Tehsildar or Sub-divisional magistrate or Metropolitan Magistrate or Sarpanch of the Panchayat, or similar other identity certificates like Electors Photo Identity Card or AADHAAR card; and

(ii) documentary evidence of identity and residence of the proposed donor, ration card or voters identity card or passport or driving license or PAN card or bank account and family photograph depicting the proposed donor and the proposed recipient along with another near relative, or similar other identity certificates like AADHAAR Card (issued by **Unique Identification Authority of India**).

(2) If in the opinion of the competent authority, the relationship is not conclusively established after evaluating the above evidence, it may in its discretion direct further medical test, namely, Deoxyribonucleic Acid (DNA) Profiling.

(3) The test referred to in sub-rule (2) shall be got done from a laboratory accredited with National Accreditation Board for Testing and Calibration Laboratories and certificate shall be given in Form 5.

(4) If the documentary evidences and test referred to in sub-rules (1) and (2), respectively do not establish a genetic relationship between the donor and the recipient, the same procedure be adopted on preferably both or at least one parent, and if parents are not available, the same procedure be adopted on such relatives of donor and recipient as are available and are willing to be tested, failing which, genetic relationship between the donor and the recipient will be deemed to have not been established.

(5) Where the proposed transplant is between a married couple the competent authority or Authorisation Committee (in case donor or recipient is a foreigner) must evaluate the factum and duration of marriage and ensure that documents such as marriage certificate, marriage photograph etc. are kept for records along with the information on the number and age of children and a family photograph depicting the entire family, birth certificate of children containing the particulars of parents and issue a certificate in Form 6 (for spousal donor).

(6) Any document with regard to the proof of residence or domicile and particulars of parentage should be relatable to the photo identity of the applicant in order to ensure that the documents pertain to the same person, who is the proposed donor and in the event of any inadequate or doubtful information to this effect, the Competent Authority or Authorisation Committee as the case may be, may in its discretion seek such other information or evidence as may be expedient and desirable in the peculiar facts of the case.

(7) The medical practitioner who will be part of the organ transplantation team for carrying out transplantation operation shall not be a competent authority of the transplant hospital.

(8) The competent authority may seek the assistance of the Authorisation Committee in its decision making, if required.

19. Procedure in case of transplant other than near relatives.—

Where the proposed transplant is between other than near relatives and all cases where the donor or recipient is foreign national (irrespective of them being near relative or otherwise), the

approval will be granted by the Authorisation Committee of the hospital or if hospital based Authorisation Committee is not constituted, then by the District or State level Authorisation Committee.

20. Procedure in case of foreigners.—

When the proposed donor or the recipient are foreigners;

(a) a senior Embassy official of the country of origin has to certify the relationship between the donor and the recipient as per Form 21 and in case a country does not have an Embassy in India, the certificate of relationship, in the same format, shall be issued by the Government of that country;

(b) the Authorisation Committee shall examine the cases of all Indian donors consenting to donate organs to a foreign national (who is a near relative), including a foreign national of Indian origin, with greater caution and such cases should be considered rarely on case to case basis:

Provided that the Indian living donors wanting to donate to a foreigner other than near relative shall not be considered.

21. Eligibility of applicant to donate.— In the course, of determining eligibility of the applicant to donate, the applicant should be personally interviewed by the Authorisation Committee which shall be videographed and minutes of the interview shall be recorded.

22. Precautions in case of woman donor.—

In case where the donor is a woman, greater precautions ought to be taken and her identity and independent consent should be confirmed by a person other than the recipient.

23. Decision of Authorisation Committee.— (1) The Authorisation Committee (which is applicable only for living organ or tissue donor)should state in writing its reason for rejecting or approving the application of the proposed living donor in the prescribed Form 18 and all such approvals should be subject to the following conditions, namely:-

(i) the approved proposed donor would be subjected to all such medical tests as required at the relevant stages to determine his or her biological capacity and compatibility to donate the organ in question;

(ii) the physical and mental evaluation of the donor has been done to know whether he or she is in proper state of health and it has been certified by the registered medical practitioner in Form 4 that he or she is not mentally challenged and is fit to donate the organ or tissue:

Provided that in case of doubt for mentally challenged status of the donor the registered medical practitioner or Authorisation Committee may get the donor examined by psychiatrist;

(iii) all prescribed forms have been and would be filled up by all relevant persons involved in the process of transplantation;

(iv) all interviews to be video recorded.

(2) The Authorisation Committee shall expedite its decision making process and use its discretion judiciously and pragmatically in all such cases where, the patient requires transplantation on urgent basis.

(3) Every authorised transplantation centre must have its own website and the Authorisation Committee is required to take final decision within twenty four hours of holding the meeting for grant of permission or rejection for transplant.

(4) The decision of the Authorisation Committee should be displayed on the notice board of the hospital or Institution immediately and should reflect on the website of the hospital or Institution within twenty four hours of taking the decision, while keeping the identity of the recipient and donor hidden.

24. Registration of hospital or tissue bank.— (1) An application for registration shall be made to the Appropriate Authority as specified in Form 12 or Form 13 or Form 14 or Form 15, as applicable and the application shall be accompanied by fee as specified below, payable to the Appropriate Authority by means of a bank draft, which may be revised, if necessary by the Central or State Government, as the case may be:-

(i) for Organ or Tissue or Cornea Transplant Centre: Rupees ten thousand;

(ii) for Tissue or Eye Bank: Rupees ten thousand;

(iii) for Non-Transplant Retrieval Centre: Nil.

(2) The Appropriate Authority shall, after holding an inquiry and after satisfying itself that the applicant has complied with all the requirements, grant a certificate of registration as specified in Form 16 and it shall be valid for a period of five years from the date of its issue and shall be renewable.

(3) Before a hospital is registered under the provisions of this rule, it shall be mandatory for the hospital to appoint a transplant coordinator.

25. Renewal of registration of hospital or tissue bank.— (1) An application for the renewal of a certificate of registration shall be made to the Appropriate Authority at least three months prior to the date of expiry of the original certificate of registration and shall be accompanied by a fee as specified below, payable to the Appropriate Authority by means of a bank draft, which may be revised, if necessary by the Central or State Government, as the case may be,-

(i) for Organ or Tissue or Cornea Transplant Centre: Rupees five thousand;

(ii) for Tissue or Eye Bank: Rupees five thousand;

(iii) for Non-Transplant Retrieval Centre: Nil.

(2) A renewal certificate of registration shall be as specified in Form 17 and shall be valid for a period of five years.

(3) If, after an inquiry including inspection of the hospital or tissue bank and scrutiny of its past performance and after giving an opportunity to the applicant, the Appropriate Authority is satisfied that the applicant, since grant of certificate of registration under sub-rule (2) of rule 24 has not complied with the requirements of the Act and these rules and the conditions subject to which the certificate of registration has been granted, shall, for reasons to be recorded in writing, refuse to grant renewal of the certificate of registration.

26. Conditions and standards for grant of certificate of registration for organ or tissue transplantation centres.— (1) No hospital shall be granted a certificate of registration for organ transplantation unless it fulfills the following conditions and standards, namely:-

A. General manpower requirement specialised services and facilities:

(a) Twenty-four hours availability of medical and surgical, (senior and junior) staff;

(b) twenty-four hours availability of nursing staff (general and specialty trained);

(c) twenty-four hours availability of Intensive Care Units with adequate equipment staff and support system, including specialists in anesthesiology and intensive care;

(d) twenty-four hours availability of blood bank (in house or access), laboratory with multiple discipline testing facilities including but not limited to Microbiology, Bio-Chemistry, Pathology, Hematology and Radiology departments with trained staff;

(e) twenty-four hours availability of Operation Theater facilities (OT facilities) for planned and emergency procedures with adequate staff, support system and equipment;

(f) twenty-four hours availability of communication system, with power backup, including but not limited to multiple line telephones, public telephone systems, fax, computers and paper photo-imaging machine;

(g) experts (other than the experts required for the relevant transplantation) of relevant and associated specialties including but not limited to and depending upon the requirements,

the experts in internal medicine, diabetology, gastroenterology, nephrology, neurology, pediatrics, gynecology, immunology and cardiology, etc., shall be available in the transplantation centre;

(h) one medical expert for respective organ or tissue transplant shall be available in the transplantation hospital; and

(i) Human Leukocyte Antigen (HLA) matching facilities (in house or outsourced) shall be available.

B. Equipments:

Equipments as per current and expected scientific requirements specific to organ (s) or tissue (s) being transplanted and the transplant centre should ensure the availability of the accessories, spare-parts and back-up, maintenance and service support system in relation to all relevant equipments.

C. Experts and their qualifications:

(a) Kidney Transplantation:
M.S. (Gen.) Surgery or equivalent qualification with three years post M.S. training in a recognised transplant center in India or abroad and having attended to adequate number of renal transplantation as an active member of team;

(b) Transplantation of liver and other abdominal organs:
M.S. (Gen.) Surgery or equivalent qualification with three years post M.S. experience in the speciality and having one year training in the respective organ transplantation as an active member of team in an established transplant center;

(c) Cardiac, Pulmonary, Cardio-Pulmonary Transplantation:
M.Ch. Cardio-thoracic and vascular surgery or equivalent qualification in India or abroad with at least three years' experience as an active member of the team performing an adequate number of open heart operations per year and well-versed with Coronary by-pass surgery and Heart-valve surgery;

(d) the hospital registered under Clinical Establishment (Registration and Regulation) Act, 2010 (23 of 2010) shall also follow the minimum standards prescribed in respect of manpower, equipment, etc., as prescribed under that Act;

(e) the hospital registered shall have to maintain documentation and records including reporting of adverse events.

(2) No hospital shall be granted a certificate of registration for tissue transplantation under the Act unless it fulfills the following conditions and standards, namely:-

(a) Cornea Transplantation:
M.D. or M.S. or Diploma (DO) in ophthalmology or equivalent qualification with three months post M.D. or
M.S or DO training in Corneal transplant operations in a recognised hospital or institution;

(b) Other tissues such as heart valves, skin, bone, etc.:
Post graduate degree (MD or MS) or equivalent qualification in the respective specialty with three months post M.D. or M.S training in a recognised hospital carrying out respective tissue transplant operations and for heart valve transplantation, and the qualification and experience of expert shall be MCh degree in Cardiothoracic and Vascular Surgery (CTVS) or equivalent qualification with three months post MCh training in a recognised hospital carrying out heart valve transplantation;

(c) the Hospital registered under Clinical Establishment (Registration and Regulation) Act, 2010(23 of 2010) shall also follow the minimum standards prescribed in respect of manpower, equipment, etc., as prescribed under that Act;

(d) the Hospital registered shall have to maintain documentation and records including reporting of adverse events.

27. Conditions and standards for grant of certificate of registration for organ retrieval centres.—

(1) The retrieval center shall be registered only for the purpose of retrieval of organ from deceased donors and the organ retrieval centre shall be a hospital having Intensive Care Unit (ICU) facilities along with manpower, infrastructure and equipment as required to diagnose and maintain the brain-stem dead person and to retrieve and transport organs and tissues including the facility for their temporary storage.

(2) All hospitals registered as transplant centres shall automatically qualify as retrieval centres.

(3) The retrieval centre should have linkages with nearby Government hospital designated for post-mortem, for retrieval in medico-legal cases.

(4) Registration of hospital for surgical tissue harvesting from deceased person and for surgical tissue residues, that are routinely discarded, shall not be required.

28. Conditions and standards for grant of certificate of registration for tissue banks.—

A. Facility and premises:

(1) Facilities must conform to the standards and guidelines laid down for the purpose and the States and Union territories may have separate registration fee and procedure to keep track of their tissue bank activities.

(2) The respective State or Union territory Appropriate Authority may constitute an expert committee for advising on the matter related to tissue specific standards and related issues.

(3) The tissue bank must have written guidelines and standard operating procedures for maintenance of its premises and facilities which include-

(a) controlled access;
(b) cleaning and maintenance systems;
(c) waste disposal;
(d) health and safety of staff;
(e) risk assessment protocol; and
(f) follow up protocol.

(4) Equipments as per scientific requirements specific to tissue (s) being procured, processed, stored and distributed and the tissue bank should ensure the availability of the accessories, spare-parts and back-up, maintenance and service support for all equipments.

(5) Air particle count and microbial colony count compliance shall be ensured for safety where necessary.

(6) Storage area shall be designated to avoid contact with chemicals or atmospheric contamination and any known source of infection.

(7) Storage facility shall be separate and distinguish tissues, held in quarantine, released and rejected.

B. Donor screening:

(8) Complete screening of donor must be conducted including medical or social history and serological evaluation for medical conditions or disease processes that would contraindicate the donation of tissues and the report of corneas or eyes not found suitable for transplantation and their alternate use shall be certified by a committee of two Ophthalmologists.

C. Laboratory tests:

(9) Facility for relevant Laboratory tests for blood and tissue samples shall be available and testing of blood and tissue samples shall begin at Donor Screening and continue during

retrieval and throughout processing.

D. Procurement and other procedures:

(10) Procurement of tissue must be carried out by registered health care professionals or technicians having necessary experience or special training.

(11) Consent for the procurement shall be obtained.

(12) Procurement records shall be maintained.

(13) Standard operating procedure for following shall be followed, namely :-

(a) procurement or Retrieval and transplantation;
(b) processing and sterilisation;
(c) packaging, labeling and storage;
(d) distribution or allocation;
(e) transportation; and
(f) reporting of serious adverse reactions.

E. Documentation and Records:

(14) A log of tissue received and distributed shall be maintained to enable traceability from the donor to the tissue and the tissue to the donor and the records shall also indicate the dates and the identities of the staff performing specific steps in the removal or processing or distribution of the tissues.

F. Data Protection and Confidentiality:

(15) A unique donor identification number shall be used for each donor, and access to donor records shall be restricted.

G. Quality Management:

(16) The Quality Management System shall define quality control procedures that include the following, namely:-

(a) environmental monitoring;
(b) equipment maintenance and monitoring;
(c) in –process controls monitoring;
(d) internal audits including reagent and supply monitoring;
(e) compliance with reference standards, local regulations, quality manuals or documented standard operating procedures; and
(f) monitoring work environment.

H. Recipient Information:

(17) All tissue recipients shall be followed up and prompt and appropriate corrective and preventive actions taken in case of adverse events.

29. Qualification, role, etc., of transplant coordinator.— (1) The transplant coordinator shall be an employee of the registered hospital having qualification such as:

(a) graduate of any recognised system of medicine; or
(b) Nurse; or
(c) Bachelor's degree in any subject and preferably Master's degree in Social work or Psychiatry or Sociology or Social Science or Public Health

(2) The concerned organisation or institute shall ensure initial induction training followed by retraining at periodic interval and the transplant coordinator shall counsel and encourage the family members or near relatives of the deceased person to donate the human organ or tissue including eye or cornea and coordinate the process of donation and transplantation.

(3) The transplant coordinator or counselor in a hospital registered for eye banking shall also have qualification specified in sub-rule (1).

30. Advisory committee of the Central or State Government to aid and advise appropriate

authority.— (1) The Central Government and the State Government, as the case may be, shall constitute by notification an Advisory Committee under Chairpersonship of administrative expert not below the rank of Secretary to the State Government for a period of two years to aid and advise the Appropriate Authority and the two medical experts referred to in clause(b) of sub-section(2) of section 13A of the Act shall possess a postgraduate medical degree and at least five years' experience in the field of organ or tissue transplantation.

(2) The terms and conditions for appointment to the Advisory Committee are as under:

(a) the Chairperson and members of the Committee shall be appointed for a period of two years;

(b) the Chairperson and members of the Committee shall be entitled to the air fare and other allowances to attend the meeting of the Committee equivalent to the officer of the level of the Joint Secretary to the Government of India;

(c) the Central Government or State Government or Union territory Administration shall have full powers to replace or remove the Chairperson and the members in cases of charges of corruption or any other charges after giving a reasonable opportunity of being heard;

(d) the Chairperson and members can also resign from the Committee for personal reasons;

(e) there shall not be a corruption or criminal case pending against Chairperson and members at the time of appointment;

(f) the Chairperson or any of the members shall cease to function if charges have been framed against him or her in a corruption or criminal case after having been given a reasonable opportunity of being heard.

31. Manner of establishing National or Regional or State Human Organs and Tissues Removal and Storage Networks and their functions.— (1) There shall be an apex national networking organisation at the centre, as the Central Government may by notification specify.

(2) There shall also be regional and State level networking organisations where large number of transplantation of organ(s) or tissue (s) are performed as the Central Government may by notification specify.

(3) The State units would be linked to hospitals, organ or tissue matching laboratories and tissue banks within their area and also to regional and national networking organisations.

(4) The broad principles of organ allocation and sharing shall be as under**,—**

(a) The website of the transplantation center shall be linked to State or Regional cum State or National networks through an online system for organ procurement, sharing and transplantation.

(b) patient or recipient may get registered through any transplant centre, but only one centre of a State or region (if there is no centre in the State) and his or her details shall be made available online to the networking organisations, who shall allocate the registration number, which shall remain same even if patient changes hospital;

(c) the allocation of the organ to be shared, is to be decided by the State networking organization and by the National networking organization in case of Delhi;

(d) all recipients are to be listed for requests of organs from deceased donors, however priority is to be given in following order, namely:-

(i) those who do not have any suitable living donor among near relatives;

(ii) those who have a suitable living donor available among near relatives but the donor has refused in writing to donate; and

(iii) those who have a suitable living donor available and who has also not refused to donate in writing;

(e) sequence of allocation of organs shall be in following order: State list----Regional List-

----National List---- Person of Indian Origin-------Foreigner;

(f) the online system of networking and framework and formats of national registry as mentioned under rule 32 shall be developed by the apex networking organisation which shall be followed by the States Governments or Union territory Administrations and the allocation criteria may be State specific which shall be finalised and determined by the State Government, in consultation with the State level networking organisation, wherever such organisation exists:

Provided that the organ sharing and networking policy of States or locations of hospitals shall not be binding on the Armed Forces Medical Services (AFMS) and the armed forces shall be free to have their own policy of organ or tissue allocation and sharing, and the Director General Armed Forces Medical Services shall have its own networking between the Armed Forces Medical Services hospitals, who shall be permitted to accept organs when available from hospitals with in their State jurisdiction.

(5) The networking organisations shall coordinate retrieval, storage, transportation, matching, allocation and transplantation of organs and tissues and shall develop norms and standard operating procedures for such activities and for tissues to the extent possible.

(6) The networking organisations shall coordinate with respective State Government for establishing new transplant and retrieval centres and tissue banks and strengthening of existing ones.

(7) There shall be designated organ and tissue retrieval teams in State or District or institution as per requirement, to be constituted by the State or Regional networking organisation.

(8) For tissue retrieval, the retrieval teams shall be formed by the State Government or Union territory Administration where ever required.

(9) Networking shall be e-enabled and accessible through dedicated website.

(10) Reference or allocation criteria would be developed and updated regularly by networking organisations in consultation with the Central or State Government, as the case may be.

(11) The networking organisation(s) shall undertake Information Education and Communication (IEC) Activities for promotion of deceased organ and tissue donation.

(12) The networking organisation(s) shall maintain and update organ or tissue Donation and Transplant Registry at respective level.

32. Information to be included in National Registry regarding donors and recipients of human organ and tissue.— The national registry shall be based on the following, namely:-

Organ Transplant Registry:

(1) The Organ Transplant Registry shall include demographic data about the patient, donor, hospitals, recipient and donor follow up details, transplant waiting list, etc., and the data shall be collected from all retrieval and transplant centers.

(2) Data collection frequency, etc., will be as per the norms decided by the Advisory Committee which may preferably be through a web-based interface or paper submission and the information shall be maintained both specific organ wise and also in a consolidated format.

(3) The hospital or Institution shall update its website regularly in respect of the total number of the transplantations done in that hospital or institution along with reasonable detail of each transplantation and the same data should be accessible for compilation, analysis and further use by authorised persons of respective State Governments and Central Government.

(4) Yearly reports shall be published and also shared with the contributing units and other stakeholders and key events (new patients, deaths and transplants) shall be notified as soon as they occur in the hospital and this information shall be sent to the respective networking

organisation, at least monthly.

Organ Donation Registry:

(5) The Organ Donation Registry shall include demographic information on donor (both living and deceased), hospital, height and weight, occupation, primary cause of death in case of deceased donor, associated medical illnesses, relevant laboratory tests, donor maintenance details, driving license or any other document of pledging donation, donation requested by whom, transplant coordinator, organs or tissue retrieved, outcome of donated organ or tissue, details of recipient, etc.

Tissue Registry:

(6) The Tissue Registry shall include demographic information on the tissue donor, site of tissue retrieval or donation, primary cause of death in case of deceased donor, donor maintenance details in case of brain stem dead donor, associated medical illnesses, relevant laboratory tests, driving license or any other document pledging donation, donation requested by whom, identity of counsellors, tissue(s) or organ(s) retrieved, demographic data about the tissue recipient, hospital conducting transplantation, transplant waiting list and priority list for critical patients, if these exist, indication(s) for transplant, outcome of transplanted tissue, etc.

(7) Yearly reports in respect of National Registry shall be published and also shared with the contributing units and other stakeholders

Pledge for organ or tissue donation after death:

(8) Those persons, who, during their lifetime have pledged to donate their organ(s) or tissue(s) after their death, shall in Form 7 deposit it in paper or electronic mode to the respective networking organisation(s) or institution where the pledge is made, who shall forward the same with the respective networking organisation and the pledger has the option to withdraw the pledge through intimation.

(9) The Registry will be accessible on-line through dedicated website and shall be in conformation to globally maintained registry (ies), besides having national, regional and State level specificities.

(10) National or regional registry shall be compiled based on similar registries at State level.

(11) The identity of the people in the database shall not be put in public domain and measures shall be taken to ensure security of all collected information.

(12) The information to be included shall be updated as per prevalent global practices from time to time.

33. Appeal.— (1) Any person aggrieved by an order of the Authorisation Committee under sub-section (6) of section 9 or by an order of the Appropriate Authority under sub-section (2) of section 15 or sub-section (2) of section 16 of the Act, may, within thirty days from the date of receipt of the order, prefer an appeal to the Central Government in case of the Union territories and respective State Government in case of States.

(2) Every appeal shall be in writing and shall be accompanied by a copy of the order appealed against.

FORM 1

For organ or tissue donation from identified living near related donor

(to be completed by him or her) (See rules 3 and 5(3)(a))

My full name (proposed donor) is ……. and this is my photograph

Photograph of the Donor (Attested by Notary Public across the photo after affixing)

To be affixed here.

My permanent home address is ……Tel: …….. My present address for correspondence is ……..……Tel:…… Date of birth……. (day/month/year)

I enclose copies of the following documents: (attach attested photocopy of at least two of following relevant documents to indicate your near relationship):

- Ration/Consumer Card number and Date of issue and place:……
  and/or
- Voter's I-Card number, date of issue, Assembly constituency……
  and/or
- Passport number and country of issue……..
  and/or
- Driving License number, Date of issue, licensing authority……
  and/or
- Permanent Account Number (PAN)……
  and/or
- AADHAAR No. …….
  and/or
- Any other valid proof of identity and address reflecting near relationship …….

I authorise removal for therapeutic purposes and consent to donate my …… (Name of organ/tissue) to my relative …….. (Specify son/daughter/ father/ mother/brother/sister/grand-father/grand-mother/grand-son/grand-daughter), whose particulars are as follows and name is …… and who was born on ……..... (day/month/year)

To be affixed here.

Photograph of the Recipient (Attested by Notary Public across the photo after affixing)

The copies of following documents of recipient are enclosed (attach attested photocopy of at least two relevant documents to indicate your near relationship):

- Ration/Consumer Card number and Date of issue and place:……
  and/ or
- Voter's I-Card number, date of issue, Assembly constituency……
  and/or
- Passport number and country of issue……..
  and/ or
- Driving License number, Date of issue, licensing authority…….
  and/or
- Permanent Account Number (PAN) ……
  and/or
- AADHAAR No (Issued by Unique Identification Authority of India)……
  and/or
- *Any* other valid proof of identity and address reflecting near relationship ……

I solemnly affirm and declare that:

Sections 2, 9 and 19 of The Transplantation of Human Organs Act, 1994 have been explained to me and I confirm that:

1. I understand the nature of criminal offences referred to in the sections.
2. No payment as referred to in the sections of the Act has been made to me or will be made to me or any other person.
3. I am giving the consent and authorisation to remove my …….. (name of organ/tissue) of my own free will without any undue pressure, inducement, influence or allurement.
4. I have been given a full explanation of the nature of the medical procedure involved and the risks involved for me in the removal of my …….. (name of organ)/tissue). That explanation was given by ……(name of registered medical practitioner)
5. I understand the nature of that medical procedure and of the risks to me as explained by that practitioner.
6. I understand that I may withdraw my consent to the removal of that organ at any time before the operation takes place.
7. I state that particulars filled by me in the form are true and correct to the best of my knowledge and belief and nothing material has been concealed by me.……

Date

Signature of the prospective donor
(Full Name)

Note: To be sworn before Notary Public, who while attesting shall ensure that the person/persons swearing the affidavit(s) signs(s) on the Notary Register, as well.

FORM 2

For organ or tissue donation by living spousal donor

(To be completed by him/her) (See rules 3, 5(3)(a) and 5(3)(d))

My full name (proposed donor) is …… and this is my photograph

Photograph of the Donor (Attested by Notary Public across the photo after affixing)

To be affixed here

My permanent home address is ……..… …… Tel: ……..…….. My present address for correspondence is…… …… Tel: ……. Date ……..(day/month/year)

I authorize removal for therapeutic purposes and consent to donate my.....(Name of organ) to my husband/wife…….. …… whose.....particulars are as follows and full name is ……. and .....who was born on …… (Day/month/year):

Photograph of the Recipient (Attested by Notary Public across the photo after affixing)

To be affixed here

I enclose copies of the following documents **(attach attested photocopy of at least two of following relevant documents to indicate the spousal relationship):**

- Ration/Consumer Card number and Date of issue and place:……
  and/or
- Voter's Identity-Card number, date of issue, Assembly constituency……..
  and/or
- Passport number and country of issue……
  and/or
- Driving License number, Date of issue, licensing authority……
  and/or
- Permanent Account Number (PAN) ……
  and/or
- AADHAAR No. (issued by Unique Identification Authority of India) ……
  and/or
- Any other proof of identity and address establishing spousal relationship ……

I submit the following as evidence of being married to the recipient:-

(a) A certified copy of a marriage certificate

OR

(b) An affidavit of a 'near relative' confirming the status of marriage to be sworn before Class-I Magistrate/Notary Public.

(c) Family photographs

(d) Letter from Head of Gram Panchayat / Tehsildar / Block Development Officer/Member of Legislative Assembly/Member of Legislative Council (MLC)/Member of Parliament with seal certifying factum and status of marriage.

OR

(e) Other credible evidence

I solemnly affirm and declare that sections 2, 9 and 19 of the Transplantation of Human Organs Act, 1994 (42 of 1994), have been explained to me and I confirm that

1. I understand the nature of criminal offences referred to in the sections.
2. No payment of money or money's worth as referred to in the Sections of the Act has been made to me or will be made to me or any other person.
3. I am giving the authorisation to remove my……...(organ) and consent to donate the same of my own free will without any undue pressure, inducement, influence or allurement.
4. I have been given a full explanation of the nature of the medical procedure involved and the risks involved for me in the removal of my …….. (organ). That explanation was given by…….(name of registered medical practitioner).
5. I understand the nature of that medical procedure and of the risks to me as explained by that practitioner.
6. I understand that I may withdraw my consent to the removal of that organ at any time before the operation takes place.
7. I state that particulars filled by me in the form are true and correct to to the best of my knowledge and nothing material has been concealed by me…….

Signature of the prospective donor
Date
(Full Name)

Note: To be sworn before Notary Public, who while attesting shall ensure that the person/persons swearing the affidavit(s) signs(s) on the Notary Register, as well

FORM 3

For organ or tissue donation by other than near relative living donor

(To be completed by him/her) (See rules 3, (3)(a) and 5(3)(e))

My full name is ……
and this is my photograph

Photograph of the Donor
(Attested by Notary Public
across the photo after affixing)

To be affixed here

My permanent home address is ……
Tel: ……. Date of birth …… (day/month/year)
My present address for correspondence is ……... ….
……
Tel:…….. Date of birth …… (day/month/year)

I enclose copies of the following documents: (attach attested photocopy of at least two of following relevant documents to prove your identity):

- Ration/Consumer Card number and Date of issue and place: ..……. (Photocopy attached)

and/or

- Voter's I-Card number, date of issue, Assembly constituency …… (Photocopy attached)

and/or

- Passport number and country of issue …… (Photocopy attached)

and/or

- Driving Licence number, Date of issue, licensing authority……(Photocopy attached)

and/or

- PAN……...

and/or

- AADHAAR No.…… .

and/or

- Other proof of identity and address …….

Details of last three years income and vocation of donor (enclose documentary evidence)
……
……

I authorize removal for therapeutic purposes and consent to donate my ……..…… (Name of organ/tissue) to a person whose full name …… ……and who was born on ……..(day/month/year) and whose particulars are as follows:

Photograph of the Recipient
(Attested by Notary Public across
the Photo after affixing)

To be affixed here

(attach attested photocopy of at least two relevant documents to prove identity of recipient)

- Ration/Consumer Card number and Date of issue and place:…… (Photocopy attached)

and/or

- Voter's I-Card number, date of issue, Assembly constituency……(Photocopy attached)

and/or

- Passport number and country of issue…… (Photocopy attached)

and/or

- Driving Licence number, Date of issue, licensing authority…… (Photocopy attached)

and/or

- PAN……...

and/or

- AADHAAR No. …….

and/or

- Other proof of identity and address …….

I solemnly affirm and declare that sections 2, 9 and 19 of the Transplantation of Human Organs Act, 1994 (42 of 1994), have been explained to me and I confirm that

1. I understand the nature of criminal offences referred to in the Sections.
2. No payment of money or money's worth as referred to in the Sections of the Act has been made to me or will be made to me or any other person.
3. I am giving the consent and authorisation to remove my ……(name of organ/tissue) of my own free will without any undue pressure, inducement, influence or allurement.
4. I have been given a full explanation of the nature of the medical procedure involved and the risks involved for me in the removal of my …….. (name of organ/tissue). That explanation was given by ……(name of registered medical practitioner).
5. I understand the nature of that medical procedure and of the risks to me as explained by the practitioner.
6. I understand that I may withdraw my consent to the removal of that organ at any time before the operation takes place.
7. I state that particulars filled by me in the form are true and correct to the best of my knowledge and nothing material has been concealed by me. ……

Signature of the prospective donor
Date
(Full Name)

Note: To be sworn before Notary Public, who while attesting shall ensure that the person/ persons swearing the affidavit(s) signs(s) on the Notary Register, as well.

FORM 4

For certification of medical fitness of living donor

(To be given by the Registered Medical Practitioner)

[See proviso to rule 5(3)(b)]

I, Dr……..…….. possessing qualification of registered as medical practitioner at serial no. …….. by the … … … . … … … … … … … … Medical Council, certify that I have examined Shri/ Smt./ Km. ……..…… S/o, D/o, W/o Shri …… aged …… who has given informed consent for donation of his/her…….. (Name of the organ) to Shri/Smt./Km …….. who is a 'near relative' of the donor/other than near relative of the donor and has been approved by the competent authority or Authorisation Committee (as the case may be) and it is certified that the said donor is in proper state of health, not mentally challenged * and is medically fit to be subjected to the procedure of organ or tissue removal.

Place: …….

Signature of Doctor:…….

Date: …….

Seal

To be affixed (pasted) here	To be affixed (pasted) here
Photograph of the Donor (Attested by doctor)	Photograph of the recipient (Attested by the doctor)

The signatures and seal should partially appear on photograph and document without disfiguring the face in photograph

* In case of doubt for mentally challenged status of the donor, the Registered Medical Practitioner may get the donor examined by psychiatrist.

FORM 5

For certification of genetic relationship of living donor with recipient

(To be filled by the head of Pathology Laboratory certifying relationship)

[See rules 5(3)(c) and 18(3)]

I, Dr./Mr./Mr/Miss. …….. working as at …… and possessing qualification of …… certify that Shri/ Smt./ Km. ……S/o, D/o, W/o Shri/ Smt. ……..… aged ……..…. the donor and Shri/ Smt. …… S/o, D/o, W/o Shri/Smt……..…… aged the prospective recipient of the organ to be donated by the said donor are related to each other as brother/ sister/ mother/father/son/daughter, grandmother, grandfather, grandson and granddaughter as per their statement. The fact of this relationship has been established / not established by the results of the tests for DNA profiling. The results of the tests are attached.

Signature
(To be signed by the Head of the Laboratory)
Seal

Place…….
Date……

FORM 6

For spousal living donor

(to be filled by competent authority and Authorisation Committee, of the hospital or district or state in case of foreigners)*

[See rule 18(2)]

I, Dr./Mr./Mrs/Miss. …… possessing qualification of …… registered as medical practitioner at serial No.……by the……Medical Council, certify that:- Mr…….S/o…….aged resident of…… and Mrs D/o,W/o…… aged……..resident of …….. are related to each other as spouse according to the statement given by them and their statement has been confirmed by means of following evidence before effecting the organ removal from the body of the said Shri/Smt/

(Applicable only in the cases where considere necessary).

OR

In case the Clinical condition of Shri/Smt …… mentioned above is such that recording of his/her statement is not practicable, reliance will be placed on the documentary evidence(s). (mention documentary evidence(s) here).....

a. Marriage certificate indicate date of marriage
b. Marriage photographs
c. Date when transplantation was advised by the hospital (to be compared with duration of marriage):
d. Number and age of children and their birth certificates
e. Any other document

Signature of *competent authority*/Authorisation committee in case of foreigners along with Seal/Stamp*
Place ……
Date …….

*Director or Medical Superintendent or In Charge of the hospital or the internal committee of the hospital formed for the purpose.as defined under the rules of Transplantation of Human Organ Act, 1994(42 of 1994).

FORM 7

For organ or tissue pledging

(To be filled by individual of age 18 year or above)

[See rule 5(4)(a)]

ORGAN(S) AND TISSUE(S) DONOR FORM

(To be filled in triplicate)

Registration Number (To be allotted by Organ Donor Registry)…….……

I……S/o,D/o,W/o…… aged…… and date of birth resident of……...…… in the presence of persons mentioned below hereby unequivocally authorise the removal of following organ(s) and/or tissue(s), from my body after being declared brain stem dead by the board of medical experts and consent to donate the same for therapeutic purposes.

Please tick as applicable

		(Following tissues can also be donated after brain stem death as well as cardiac death)	
Heart	☐	Corneas/Eye Balls	☐
Lungs	☐	Skins	☐
Kidneys	☐	Bones	☐
Liver	☐	Hearts Valves	☐
Pancreas	☐	Blood Vessels	☐
Any other Organ (PI. specify)	☐	Any other Tissue (PI. Specify)	☐
All Organ		All Tissues	

My blood group is (if known)……

Signature of Pledger.....
Address for correspondence……
Telephone No.……..
Email : …….
Dated:……

(Note: In case of online registration of pledge, one copy of the pledge will be retained by pledger, one by the institution where pledge is made and a hard copy signed by pledger and two witnesses shall be sent to the nodal networking organisation.)

(Signature of Witness 1)

1. Shri/Smt./Km.……S/o,D/o,W/o…… …… aged…….resident of …… Telephone

No.....Email:.....

(Signature of Witness 2)

2. Shri/Smt./Km.……S/o,D/o,W/o…… ……aged…….resident of ……Telephone No.....Email:..... is a near relative to the donor as …….. Dated……. Place ……..

Note: (i) Organ donation is a family decision. Therefore, it is important that you discuss your decision with family members and loved ones so that it will be easier for them to follow through with your wishes.

(ii) One copy of the pledge form/pledge card to be with respective networking organisation, one copy to be retained by institution where the pledge is made and one copy to be handed over to the pledger.

(iii) The person making the pledge has the option to withdraw the pledge.

FORM 8

For Declaration cum consent

(To be filled by near relative or lawful possessor of brain-stem dead person)

[See rules 5(1)(b), 5(4)(b) and 5(4)(d)]

DECLARATION AND CONSENT FORM

I……S/o,D/o,W/o…… aged…….resident of ……in the presence of persons mentioned below, hereby declare that:

1. I have been informed that my relative (specify relation) ..... S/o,D/o,W/o……aged…….has been declared brain-stem dead / dead.
2. To the best of my knowledge (Strike off whichever is not applicable):
   a. He/She. (Name of the deceased)..... had / had not, authorised before his/her death, the removal of ……. (Name of organ/tissue/both) of his/her body after his/her death for therapeutic purpose. The documentary proof of such authorisation is enclosed/not available
   b. He/She. (Name of the deceased) …… had not revoked the authority as at No.2 (a) above (If applicable) .
   c. There are reasons to believe that no near relative of the said deceased person has objection to any of his/her organs/tissue being used for therapeutic purposes.
3. I have been informed that in the absence of such authorisation, I have the option to either authorise or decline donation of organ/tissue/both including eye/cornea of .....(Name of the deceased) for therapeutic purposes. I also understand that if corneas/eyes are not found suitable for therapeutic purpose, then may be used for education/research.
4. I hereby authorise / do not authorize removal of his/her body organ(s) and/or tissue(s), namely *(Any organ and tissue/ Kidney /Liver /Heart /Lungs /Intestine /Cornea /Skin /Bone /Heart Valves /Any other; please specify)*……for therapeutic purposes. I also give permission for drawing of a blood sample for serology testing and am willing to share social/behavioural and medical history to facilitate proper screening of the donor for safe

transplantation of the organs/ tissues.

Date……. Signature of near relative /person in lawful possession of the dead body, and address for correspondence*.
Place ……..Telephone No.……Email: ……

* in case of the minor the declaration shall be signed by one of the parent of the minor or any near relative authorised by the parent. In case the near relative or person in lawful possession of the body refuses to sign this form, the same shall be recorded in writing by the Registered Medical Practitioner on this Form.

(Signature of Witness 1)

1.Shri/Smt./Km.……S/o,D/o,W/o…… aged…….resident of …….Telephone No..... Email: .....

(Signature of Witness 2)

2.Shri/Smt./Km.……S/o,D/o,W/o…… aged…….resident of …….. .Telephone No..... Email:.....

FORM 9

For unclaimed body in a hospital or prison

(To be completed by person in lawful possession of the unclaimed body)

[see rule 5(1)(b)]

I……S/o,D/o,W/o…… …… aged…….resident of ……having lawful possession of the dead body of Shri/Smt./Km…… S/o,D/o,W/o…… aged…….resident of …… and having known that no person has come forward to claim the body of the deceased after 48 hours of death and there being no reason to believe that any person is likely to come to claim the body I hereby, authorize removal of his/her body organ(s) and/or tissue(s), namely for therapeutic purposes.

Signature, Name, designation and Stamp of person in lawful possession of the dead body
Dated……..Place……
Address for correspondence……...
……..…
Telephone No..... Email .....

(Signature of Witness 1)

1. Shri/Smt./Km.……..…

S/o,D/o,W/o…….. aged…….resident of ……..Telephone No..... Email .....

(Signature of Witness 2)

2.
Shri/Smt./Km.……S/o,D/o,W/o…… …… aged…….resident of …… Telephone No. ……..
Email ……..……

FORM 10

For certification of brain stem death

(To be filled by the board of medical experts certifying brain-stem death)

[See rules 5(4)(c) and 5(4)(d)]

We, the following members of the Board of medical experts after careful personal examination hereby certify that Shri/Smt./Km…… aged about …… son of /wife of / daughter of Resident of …… is dead on account of permanent and irreversible cessation of all functions of the brain-stem. The tests carried out by us and the findings therein are recorded in the brain-stem death Certificate annexed hereto.

Dated…… Signature……..

1. R.M.P.- Incharge of the Hospital In which brain-stem death has occurred.
2. R.M.P. nominated from the panel of Names sent by the hospitals and approved by the Appropriate Authority.
3. Neurologist/Neuro-Surgeon
4. R.M.P. treating the aforesaid deceased person

(where Neurologist/Neurosurgeon is not available, any Surgeon or Physician and Anaesthetist or Intensivist, nominated by Medical Administrator Incharge from the panel of names sent by the hospital and approved by the Appropriate Authority shall be included)

BRAIN-STEM DEATH CERTIFICATE

(A) PATIENT DETAILS

1. Name of the patient:Mr./Ms……
   S.O./D.O./W.O. Mr./Ms……..……
   Sex……..Age……
2. Home Address:
   ……..
3. Hospital Patient Registration Number (CR No.):
   ……

4. Name and Address of next of kin or person…… responsible for the patient…… (if none exists, this must be specified) ……..…….
5. Has the patient or next of kin agreed……..
to any donation of organ and/or tissue?……..
6. Is this a Medico-legal Case? Yes….....No….....

(B) PRE-CONDITIONS:

1. Diagnosis: Did the patient suffer from any illness or accident that led to irreversible brain damage? Specify details……
……
……
Date and time of accident/onset of illness…….
Date and onset of non-reversible coma……...

2. Findings of Board of Medical Experts:

First Medical Examination Second Medical Examination

(1) The following reversible causes of coma have been excluded:
Intoxication (Alcohol)
Depressant Drugs
Relaxants (Neuromuscular blocking agents)
Primary Hypothermia
Hypovolaemic shock
Metabolic or endocrine disorders
Tests for absence of brain-stem functions

(2) Coma
(3) Cessation of spontaneous breathing
(4) Pupillary size
(5) Pupillary light reflexes
(6) Doll's head eye movements
(7) Corneal reflexes (Both sizes)
(8) Motor response in any cranial nerve distribution, any responses to stimulation of face, limb or trunk.
(9) Gag reflex
(10) Cough (Tracheal)
(11) Eye movements on caloric testing bilaterally.
(12) Apnoea tests as specified.
(13) Were any respiratory movements seen?

…… Date and time of first testing:

……Date and time of second testing: ……

This is to certify that the patient has been carefully examined twice after an interval of about six hours and on the basis of findings recorded above, Mr./Ms…….…… is declared brain-stem dead.

Date:

Signatures of members of Brain Stem Death (BSD) Certifying Board as under:

1. Medical Administrator Incharge of the hospital 2. Authorised specialist.

3. Neurologist/Neuro-Surgeon 4. Medical Officer treating the Patient.

Note.

I. Where Neurologist/Neurosurgeon is not available, then any Surgeon or Physician and Anaesthetist or Intensivist, nominated by Medical Administrator Incharge of the hospital shall be the member of the board of medical experts for brain-stem death certification.

II. The minimum time interval between the first and second testing will be six hours in adults. In case of children 6 to 12 years of age, 1 to 5 years of age and infants, the time interval shall increase depending on the opinion of the above BSD experts.

III. No.2 and No.3 will be co-opted by the Administrator Incharge of the hospital from the Panel of experts (Nominated by the hospital and approved by the Appropriate Authority).

FORM 11

APPLICATION FOR APPROVAL OF TRANSPLANTATION FROM LIVING DONOR

(To be completed by the proposed recipient and the proposed living donor)

[See rules 5(3)(d), 5(3)(e) and 10]

To be self attested across the affixed photograph without disfiguring face	To be self attested across the affixed photograph without disfiguring face
Photograph of the Donor	Photograph of the recipient

Whereas ……..……..……. S/o,D/o,W/o,Shri/Smt……

…..……...aged…….residing at ……... have been advised by my doctor……that I am suffering from …… and may be benefited by transplantation of …… into my body.

And whereas I ……. S/o, D/o, W/o, Shri/Smt……

…….. aged ……. Residing at … …….. by the following reason(s):-

a) by virtue of being a near relative i.e. ……

b) by reason of affection/attachment/other special reason as explained below :-

……
…

I would therefore like to donate my (name of the organ) ……... to Shri/Smt……..…….

We ……. ……. and ……. ……

(Donor) (Recipient)

hereby apply to competent authority / Authorisation Committee for permission for such

transplantation to be carried out.

We solemnly affirm that the above decision has been taken without any undue pressure, inducement, influence or allurement and that all possible consequences and options of organ transplantation have been explained to us.

Instructions for the applicants:-

1. Form 11 must be submitted along with the completed Form 1 or Form 2 or Form 3 as may be applicable.
2. The applicable Form i.e. Form 1 or Form 2 or Form 3 as the case may be, should be accompanied with all documents mentioned in the applicable form and all relevant queries set out in the applicable form must be adequately answered.
3. Completed Form 5 must be submitted along with the laboratory report.
4. The doctor's advice recommending transplantation must be enclosed with the application.
5. In addition to above, in case the proposed transplant is between unrelated persons, appropriate evidence of vocation and income of the donor as well as the recipient for the last three years must be enclosed with this application. It is clarified that the evidence of income does not necessarily mean the proof of income tax returns, keeping in view that the applicant(s) in a given case may not be filing income tax returns.
6. The application shall be accepted for consideration by the competent authority / Authorisation Committee only if it is complete in all respects and any omission of the documents or the information required in the forms mentioned above, shall render the application incomplete.
7. When the donor is unrelated and the donor and/or recipient belong to a State/Union Territory other than the State/Union Territory, where the transplant is intended to take place, then the Tehsildar or the officer authorised for the purpose of the domicile state of the donor or recipient as the case may be, would provide the verification certificate of domicile of donor/recipient as the case may be as per Form 20. The approval for transplantation would be considered by the authorisation committee of the State/District/hospital (as the case may be) where the transplantation is intended to be done. Such verification Certificate will not be required for near relatives including cases involving swapping of organs (permissible between near relatives only).

We have read and understood the above instructions.

Signature of the Prospective Donor	Signature of Prospective Recipient
Address for correspondence:	Address for correspondence:
Date :	Date :
Place :	Place :

FORM 12

APPLICATION FOR REGISTRATION OF HOSPITAL TO CARRY OUT ORGAN OR TISSUE TRANSPLANTATION OTHER THAN CORNEA

(To be filled by head of the institution)

(See rule 24(1))

To

The Appropriate Authority for organ transplantation……
(State or Union territory)

We hereby apply to be registered as an institution to carry out organ/tissue transplantation.

Name(s) of organ (s) or tissue (s) for which registration is required…….

The required data about the facilities available in the hospital are as follows:-

(A) HOSPITAL:

1. Name:
2. Location:
3. Government/Private:
4. Teaching/Non-teaching:
5. Approached by: Road: Yes No.
   Rail: Yes No
   Air: Yes No
6. Total bed strength: .
7. Name of the disciplines in the hospital:
8. Annual budget:
9. Patient turn-over/year:

(B) SURGICAL FACILITIES:

1. No. of beds:
2. No. of permanent staff members with their designation:
3. No. of temporary staff with their designation:
4. No. of operations done per year:
5. Trained persons available for transplantation (Please specify Organ for transplantation):

(C) MEDICAL FACILITIES:

1. No. of beds:
2. No. of permanent staff members with their designation:
3. No. of temporary staff members with their designation:
4. Patient turnover per year:
5. Trained persons available for transplantation (Please specify Organ for transplantation):
6. No. of potential transplant candidates admitted per year:

(D) ANAESTHESIOLOGY:

1. No. of permanent staff members with their designations:
2. No. of temporary staff members with their designations:
3. Name and No. of operations performed:
4. Name and No. of equipments available:
5. Total No. of operation theatres in the hospital:
6. No. of emergency operation-theatres:
7. No. of separate transplant operation theatre:

(E) I.C.U./H.D.U. FACILITIES:

1. I.C.U./H.D.U. facilities: Present……. Not present……
2. No. of I.C.U. and H.D.U. beds:

3. Trained:
   Nurses:
   Technicians:
4. Name of equipment in I.C.U.

(F) OTHER SUPPORTIVE FACILITIES:

Data about facilities available in the hospital:

(F1) LABORATORY FACILITIES:

1. No. of permanent staff with their-designations:
2. No. of temporary staff with their designations:
3. Names of the investigations carried out in the Department:
4. Name and number of equipments available:

(F2) IMAGING FACILITIES :

1. No. of permanent staff with their-designations:
2. No. of temporary staff with their designations:
3. Names of the investigations carried out in the Department:
4. Name and number of equipments available:

(F3) HAEMATOLOGY FACILITIES:

1. No. of permanent staff with their-designations:
2. No. of temporary staff with their designations:
3. Names of the investigations carried out in the Department:
4. Name and number of equipments available:

(F4) BLOOD BANK FACILITIES (Inhouse or access): Yes …… No…….

(F5) DIALYSIS FACILITIES : Yes ……
No……

(F6). Transplant coordinators (Eye Donation Counselors, in case of Cornea Transplantation):
Yes…. No….
Number Posted :
Number Trained

(F7) OTHER SUPPORTIVE EXPERT PERSONNEL:

1.	Nephrologist	Yes/No
2.	Neurologist	Yes/No
3.	Neuro-Surgeon	Yes/No
4.	Urologist	Yes/No
5.	G.I. Surgeon	Yes/No
6.	Paediatrician	Yes/No
7.	Physiotherapist	Yes/No
8.	Social Worker	Yes/No
9.	Immunologists	Yes/No
10.	Cardiologist	Yes/No
11.	Respiratory physician	Yes /No
12.	Others	Yes /No

The above said information is true to the best of my knowledge and I have no objection to any scrutiny of our facility by authorised personnel. A Bank Draft/cheque of Rs. 10000/ (for new registration) and Rs. 5000 (for renewal) in favour of___is enclosed.

Sd/-
HEAD OF THE
INSTITUTION

FORM 13

APPLICATION FOR REGISTRATION OF HOSPITAL TO CARRY OUT ORGAN/TISSUE RETRIEVAL OTHER THAN EYE/CORNEA RETRIEVAL

(To be filled by head of the institution)

(See rule 24(1))

Note: Retrieval Hospitals may also be identified based on pre-defined criteria and registered as retrieval hospital by the appropriate authority.

To

The Appropriate Authority for organ transplantation……. (State or Union territory)

We hereby apply to be registered as an institution to carry out organ/tissue retrieval. The required data about the facilities available in the hospital are as follows:-

(A) HOSPITAL:

1. Name:
2. Location:
3. Government/Private:
4. Teaching/Non-teaching:
5. Approached by: Road: Yes No.
   Rail: Yes No
   Air: Yes No
6. Total Bed Strength:
7. Name of the disciplines in the hospital:
8. Annual budget:
9. Patient turn-over/year:

(B) SURGICAL FACILITIES:

1. No. of beds:
2. No. of permanent staff members with their designation:
3. No. of temporary staff with their designation:
4. No. of operations done per year:
5. Trained persons available for retrieval (Please specify Organ and/or tissue for retrieval):

(C) MEDICAL FACILITIES:

1. No. of beds:
2. No. of permanent staff members with their designation:
3. No. of temporary staff members with their designation:
4. Patient turnover per year:
5. Trained persons available for retrieval (Please specify Organ and/or tissue for retrieval):
6. No.of critical trauma cases admitted per year.
7. No.of brain stem death declared per year.

(D) ANAESTHESIOLOGY:

1. No. of permanent staff members with their designations:
2. No. of temporary staff members with their designations:
3. Name and No. of operations performed:
4. Name and No. of equipments available:

5. Total No. of operation theatres in the hospital:
6. No. of emergency operation-theatres:
7. No. of separate retrieval operation theatre:

(E) I.C.U./H.D.U. FACILITIES:

1. I.C.U./H.D.U. facilities: Present……. Not present……
2. No. of I.C.U. and H.D.U. beds:
3. Trained:- Nurses:
   Technicians:
4. Name of equipment in I.C.U.

(F) OTHER SUPPORTIVE FACILITIES:

Data about facilities available in the hospital:

(F1) LABORATORY FACILITIES:

1. No. of permanent staff with their-designations:
2. No. of temporary staff with their designations:
3. Names of the investigations carried out in the Deptt.:
4. Name and number of equipments available:

(F2) IMAGING FACILITIES:

1. No. of permanent staff with their-designations:
2. No. of temporary staff with their designations:
3. Names of the investigations carried out in the Deptt.:
4. Name and number of equipments available:

(F3) HAEMATOLOGY FACILITIES:

1. No. of permanent staff with their-designations:
2. No. of temporary staff with their designations:
3. Names of the investigations carried out in the Deptt.:
4. Name and number of equipments available:

(F4) BLOOD BANKFACILITIES: (in house or access) Yes …….
No…….

(F5) Transplant coordinators: Yes ……. No…….
Number Posted:
Number Trained

The above said information is true to the best of my knowledge and I have no objection to any scrutiny of our facility by authorised personnel. I hereby give an undertaking that we shall make the facilities of the hospital including the retrieval team of the hospital available for retrieval of the organ/tissue as and when needed.

Sd/-
HEAD OF THE
INSTITUTION

FORM 14

APPLICATION FOR REGISTRATION OF TISSUE BANKS OTHER THAN EYE BANKS

(To be filled by head of the institution)

(See rule 24(1))

To

The Appropriate Authority for organ transplantation……. (State or Union Territory)

We hereby apply to be registered as Tissue bank , Name ……..

Name(s) of tissue (s)(Bone, heart valves, skin, cornea etc) for which Registration is required …… ……. The required data about the facilities available in the institution are as follows:-

A. General Information :

1. Name
2. Address
3. Government/Private/NGO
4. Teaching /Non- teaching
5. Approached by:

Rail:	Yes	No
Road:	Yes	No
Air:	Yes	No

6. Information Education and Communication (IEC) for Tissue Donation
7. Type of tissue bank: Auto Logons /Allograph/Both

B. DONOR SCREENING REMOVAL OF TISSUE AND STORAGE:

1. Availability of adequate trained and qualified Personnel for removal Tissue,(annex detail). Yes/No
2. Names, qualification and address of the doctors/technician who will be doing removal of tissue.(annex details) Yes/No
3. Facilities for removal of Tissues Yes/No
4. Whether register of recipient waiting list available. Yes/No
5. Telephone arrangement available. (Telephone Number) Yes/No
6. Availability of ambulance/ vehicle or funds to Pay taxi for collecting tissue from outside: Yes/No
7. Sets of instruments for removal of tissue Yes/No
8. Facilities for processing of tissue Yes/No
9. Refrigerator for preservation of tissue Yes/No
10. Special containers for preservation of tissue during transit. Yes/No
11. Suitable preservation media Yes/No
12. Any other specific requirement as per tissue Yes/No

C.PRESERVATIONS OF TISSUE

Arrangement of preservation of Tissue Yes/No

D.RECORDS

1. Arrangement for maintaining the records Yes/No
2. Arrangement for registration of cases, donors and follow up of cases. Yes/No

E.EQUIPMENT:

Instruments specific for the tissue Yes/No

F.LABORATORY FACILITIES (If the information is exhaustive please annex it)

a. Names of the investigations carried out in the department.

b. Facility for testing for :

i. Human Immunodeficiency Virus Type I and II Yes/No

ii. Hepatitis B Virus – HBc and HBs

iii. Hepatitis C Virus – HCV

iv. Syphilis – VDRL

c. If no where do you avail it ? Please mention name and address of institute.

d. Facility for culture and sensitivity of tissue Yes/No

G.OTHER PERSONNEL

1. No. of permanent staff member with their designation.
2. No. of temporary staff with their designation
3. No. of trained persons

ANY OTHER INFORMATION:

The above said information is true to the best of my knowledge and I have no objection to any scrutiny of our facility by authorised personnel. A Bank Daft/cheque of Rs. 10000/ (for new registration) and Rs. 5000 (for renewal) in favour of____is enclosed.

Sd/-
HEAD OF THE
INSTITUTION

FORM 15

APPLICATION FOR REGISTRATION OF EYE BANK, CORNEAL TRANSPLANTATION CENTRE, EYE RETRIEVAL CENTRE UNDER TRANSPLANTATION OF HUMAN ORGANS ACT

[See rule 24(1)]

I. EYE BANKING:

A.	EYE BANK and institution affiliated Ophthalmic / General Hospital	
	1. Name 2. Address 3. Government/Private/Voluntary 4. Teaching /Non- teaching 5. IEC for Eye Donation	
B.	REMOVAL OF EYE BALLS AND STORAGE:	
	1. Availability of adequate trained and qualified personnel for removal of whole globe or corneal (annex detail)	Yes/No
	2. Names, qualification and address of the designated staff who will be doing removal of whole globe / cornea retrieval. (annex details)	Yes/No
	3. Availability of following as per requirement: a. Whether register maintained for tissue request received from surgeon of corneal transplant centre.	Yes/No
	b. Telephone arrangement available. (Dedicated Telephone Number.....)	Yes/No
	c. Transport facility for collecting Eyeballs from outside:	Yes/No

	d. Sets of instruments for removal of whole globe /cornea as per requirement	Yes/No
	e. Special bottles with stands for preservation of Eye balls/ cornea during transit.	Yes/No
	f. Suitable preservation media	Yes/No
	g. Biomedical Waste Management.	Yes/No
	h. Uninterrupted Power supply.	Yes/No
C	MANPOWER: 1. Incharge / Director (Ophthalmologist) -1 2. Eye Bank Technician- 2 3. Eye Donation Counselors (EDC)-2 per attached HCRP (Hospital Cornea Retrieval Cornea Programme) Hospital, who will be posted at eye Bank. 4. Multi task Staff(MTS) -2	
D.	Space requirement for eye Banks (400sqft minimum)	Yes/No
E.	RECORDS:	
	1. Arrangement for maintaining the records	Yes/ No
	2. Arrangement for registration of pledges,/ donors and maintenance of utilization report	Yes/No
	3. Computer with internet facility and Printer	Yes/ No
F.	EQUIPMENT:	
	1. Slit Lamp Biomicroscope-1 2. Specular Microscope for Eye Bank-1 3. Laminar flow(Class II)-1 4. Sterilization facility (In-house or outsourced) 5. Refrigerator with temperature monitoring for preservation of eye balls/Cornea-1	Yes/No
G	LABORATORY FACILITIES	
	1. Facility for HIV, Hepatitis B and C testing.	Yes/No
	2. If no where do you avail it? Please mention Name and address of institute.	
	3. Facility for culture and sensitivity of Corneoscleral ring.	Yes/No
H	RENEWAL OF REGISTRATION: Period of renewal 5years after last registration. Minimum of 500 corneas to be collected in 5 years. Maintenance of eye bank standards(as per Guidelines)	
II. EYE RETRIEVAL CENTRE (ERC):		
A.	RETRIEVAL CENTRE– A Centre affiliated to an Eye Bank 1. Name 2. Address 3. Government/Private/Voluntary 4. Teaching /Non- teaching 5. Information, Education and Communication Activities for Eye Donation Name of Eye Bank to which ERC is affiliated.	
B	REMOVAL OF EYE BALLS AND STORAGE: 1. Manpower : Adequate trained and qualified personnel for removal of eye balls/cornea (annex detail): a. Incharge / Director) -1 b. Technician -1 c. MTS (Multi task Staff) -1	

	2. Transport facility(or outsource) with storage medium	
C	Names, qualification and address of the personnel who will be doing enucleation/ removal of cornea. (annex details)	
D	AVAILABILITY OF FOLLOWING: 1. Telephone. (Number) 2. Ambulance/ vehicle or funds to pay taxi for collecting eyeballs from outside: 3. Sets of instruments for removal of Eye Balls/cornea 4. Special bottles with stands for preservation of 5. Eye balls/ cornea during transit: 6. Suitable preservation media 7. Waste Disposal (Biomedical waste Management) 8. Space requirement: Designated area	
E	RECORDS 1. Arrangement for maintaining the records	
F	EQUIPMENT: 1. Sterilization facility 2. Refrigerator temperature control 24 hrs for preservation of Eye balls/ Cornea.(power back up) - 1 3. The retrieval centre is affiliated with an Eye bank and Eye Bank is only authorised to distribute corneas.	
III. CORNEAL TRANSPLANTATION CENTRE		
A	1. Name of the Transplant Centre /hospital: 2. Address: 3. Government/Private/Voluntary: 4. Teaching /Non- teaching: 5. IEC for Eye Donation: Yes/No 6. Name of the registered Eye Bank for procuring tissue:	
B	STAFF DETAILS: 1. No. of permanent staff member with their designation. (Note : Eye Surgeon's Experience : 3 month post MD/MS/DNB/DO)	
	2. No. of temporary staff with their designation	
	3. Trained persons for Keratoplasty and Corneal Transplantation with their names and qualifications: 2 (one Corneal Transplant surgeon should be on the pay roll of the Institute)	
C	Equipment : Slit lamp, Clinical Specular, Keratoplasty or intraocular instruments	
D	OT facilities	
E	Safe Storage facility	
F	Records Registration and follow up	
G	Any other information	

The above said information is true to the best of my knowledge and I have no objection to any scrutiny of our facility by authorised personnel. A Bank draft/cheque of Rs. 10000- for new registration and Rs 5000/ for renewal of registration drawn in favour of _____is enclosed.

Head of the Institute
(Name and designation)

FORM 16

CERTIFICATE OF REGISTRATION FOR PERFORMING ORGAN/TISSUE TRANSPLANTATION/RETRIEVAL AND/OR TISSUE BANKING

(See rule 24(2))

This is to certify that …….. Hospital/Tissue Bank located at …….. has been inspected and certificate of registration is granted for performing the organ/tissue retrieval/transplantation/banking of the following organ(s)/tissue(s) (mention the names) under the Transplantation of Human Organs Act, 1994 (42 of 1994):-

1. …….
2. …….
3. …….
4. …….

This certificate of registration is valid for a period of five years from the date of issue.

This permission is being given with the current facilities and staff shown in the present application form. Any reduction in the staff and/or facility must be brought to the notice of the undersigned.

Place…… Signature of Appropriate Authority……..

Date…….. Seal: ……..

FORM 17

Certificate of Renewal of Registration

(To be given by the appropriated authority on the letter head) [See rule 25(2)]

This is with reference to the application dated……. from…… (Name of the hospital/tissue bank) for renewal of certificate of registration for performing organ(s)/tissue(s) retrieval/transplantation/banking under the Transplantation of Human Organs Act, 1994 (42 of 1994).

After having considered the facilities and standards of the above-said hospital/tissue bank, the Appropriate Authority hereby renews the certificate of registration of the said hospital/tissue bank for a period of five years.

This renewal is being given with the current facilities and staff shown in the present application form. Any reduction in the staff and/or facility must be brought to the notice of the undersigned.

Place…… Signature of Appropriate Authority……..

Date…….. Seal: ……..

FORM 18

Certificate *by the Authorisation Committee of Hospital (If Hospital Authorisation committee is not available then the Authorisation Committee of the district/State) where the transplantation has to take place*

(To be issued on the letter head)

[See rules 16 and 23]

This is to certify that as per application in form-10 for transplantation of _____(Name of Organ/tissue) from living donor, other than near relative/ swap donation cases/ all foreigner under the Transplantation of Human Organs Act,1994 (42 of 1994) *submitted on by the donor and recipient, whose details and photographs are given below, along with their identifications and verification documents, the case was considered after the personal interview of donor and recipient (if medically fit to be interviewed) and their relatives as applicable by the Authorisation Committee in the meeting held on …dated……..*

Details of Recipient	*Details of Donor*
Name……..	*Name:……..*
Age……..	*Age ……..*
Sex ……..	*Sex ……..*
Father / Husband Name ……	*Father / Husband name……..*
……..	*……..*
Address: ……	*Address: ……*
……..	*……*
Hospital Reg. No ……..	*Hospital Reg. No……*

Relation of donor with Recipient ……

Recipient	*Donor*

(Photo of recipient and donor must be signed and stamped across the photo after affixing)

Permission is granted, as to the best of knowledge of the members of the committee, donation is out of love and affection and there is no financial transaction between recipient and donor and there is no pressure on / coercion of the donor.

Permission is withheld pending submission of the following documents……

……

……. Permission is not granted for the following reasons……

……

(Member)	*(Member)*	*(Member)*	*(Member)*
Name and Designation	*Name and Designation*	*Name and Designation*	*Name and Designation*

(Sign of Chairman with stamp)

(Member)	*(Member)*
Health Secretary Or Nominee	*DHS or Nominee*

Name and Designation *Name and Designation*

Date and place……

** In case of SWAP transplants, details are to be annexed*

FORM 19

Certificate by competent authority [as defined at rule 2(c)] For Indian near relative, other than spouse, cases (In case of spousal donor, Form 6 will be applicable)

[See rule 5(3)(c)]

(Format for the decision of Competent Authority)

This is to certify that as per application in Form-11 for transplantation of_____ (Name of Organ or Tissue) from living donor who is a near relative of the recipient under the Transplantation of Human Organs Act, 1994(42 of 1994), submitted on ……by the donor and recipient, whose details and photographs are given below, along with their identifications and verifications documents, the case was considered after the personal interview of donor and recipient (if medically fit to be interviewed) by the competent authority in the meeting held on ……

Details of Recipient .....Details of Donor
Name…….. .....Name:…….
Age…….. .....Age …….
Sex …… .....Sex …….
Father or Husband Name ……..... Father or Husband name…….
…… .....…….
Address: .....Address: …….
Hospital Reg. No …….. .....Hospital Reg. No……
Relation of donor with
Recipient……..…

Recipient	Donor

(Photo of recipient and donor must be signed and stamped across the photo after affixing)
Permission is granted, as to the best of knowledge of the members of the committee, donation is out of their being near relative and there is no financial transaction between recipient and donor and there is no pressure on / coercion of the donor.Permission is withheld pending submission of following documents……..……..
Permission is not granted for the following

reasons……..……

(Signature and stamp of competent authority)

Date and place…….

FORM 20

Verification certificate *in respect of domicile status of recipient or donor*

[To be issued ***by tehsildar or any other authorised officer*** *for the purpose (required only for the donor - other than near relative or recipient if they do not belong to the state where transplant hospital identified for operation is located)]*

[See rule 14]

Part I (To be filled by applicant donor or recipient separately in triplicate)

In reference to application for verification of domicile status for donation of ……..… (Name of organ/Tissue) from living donor (other than near relative) or recipient under Transplantation of Human Organ Act, 1994 (42 of 1994), submitted on (date)……. by the applicant donor or recipient, with following details and photograph , along with his or her identification and domicile status for verification

Details of Applicant Recipient or Donor

Name……..……..

Age……...… Sex……...……

Father or Husband Name ……..…

Address:……..…….

Hospital Reg. No ……...

(Recent Photo of Applicant must be signed by him or her across the photo after affixing it)

The detail of my donor or recipient are as under and I have enclosed his or her self-signed recent photograph :

Name……..…..

Age……. Sex ……

Father or Husband Name ……

Address:……..……

Hospital Reg. No ……..

Signature of Applicant

Enclosure : Self signed copy of the donor or recipient for the applicant (to be enclosed)

Part II (To be filled by the certificate issuing authority):

The above request has been examined and it is certified that the domicile status of the applicant donor or recipient mentioned as above has been verified as under:

Name …… Son or Daughter or Wife of……

resident of village or ward ……..……,Tehsil or Taluka……..District .....State or UT…… and found correct or incorrect

……

……

Date ……Place ……

Reference No

Authorised Signatory

Name and Designation

Office Stamp

2. The authorised signatory will hand over this verification certificate to the applicant or his or her representative for submission to the Chairperson of the Authorisation Committee of the hospital or district or state (as the case may be), where transplantation has to take place.

3. The authorised signatory shall keep one copy of the above verification certificate for his records and send a copy to the Secretary, Health and Family Welfare of the State Government (Attention Appropriate authority for organ transplant) for information.
4. In case of any suspicion of organ trading, the authorised signatory mentioned above or Appropriate Authority of the state may inform police for making enquiry and taking necessary action as per the Transplantation of Human Organs Act, 1994 (42 of 1994).

FORM 21

Certificate of relationship between donor and recipient in case of foreigners (To be issued by the Embassy concerned)

[See rule 20(a)]

The embassy of … … … … … … … … … … . (Name of Country) in India, is in receipt of an application received from ……(Name of Organ donor and recipient) on ……(Date) recommended by ……(Name of Government Department of country of origin) for facilitation of donation of …… ……..(Name of Organ or Tissue) from living donor ……..… (Name of donor) to the recipient … … … …… ……..…. (Name of recipient) for therapeutic purposes under the Transplantation of Human Organ Act, 1994(42 of 1994). The details of donor and recipient and photographs are as given below.

Details of Recipient	Details of Donor
Name……..	Name:…….
Age…….	Age ……..
Sex ……	Sex …….
Father or Husband Name ……	Father or Husband name……..
……	…….
Adddress:	Address:
…….	…….
…….	…….
……..	…….

Recipient Donor

(Photo of recipient and donor must be signed and stamped across the photo after affixing)

1, This is to certify that relationship between donor and Recipient is……

2. The authenticity of following enclosed identification and verification documents is certified
   a._____
   b._____

'No objection certificate' is granted, as to the best of my knowledge, the donor is donating out

of love and affection or affection and attachment towards the recipient, and there is no financial transaction between recipient and donor and there is no pressure on or coercion of the donor.

(Signature of Senior
Embassy Official)

Date: Name: …….
Place: Designation……..

[No.S.12011/28/2012-MG/MS]
ARUN K. PANDA. Jt. Secy.

Printed at and Published by the Directorate of Printing & Stationery, Government of Manipur.

Digitally signed by
Thingbaijam Binodkumar Singh
Date: 26-02-2026 16:43:14